

## Claims

1. A method of activating the immune system of a newborn animal comprising administering to the newborn animal within the first 24 hours of age, an amount of a mycobacterial cell wall extract, wherein the amount is effective to activate the immune system of the newborn animal.
2. A method of activating the immune system of a newborn animal comprising administering to the newborn animal between 1 hour and 4 days of age, an amount of a mycobacterial cell wall extract, wherein the amount is effective to activate the immune system of the newborn animal.
3. A method of activating the immune system of a newborn animal comprising administering to the newborn animal between 1 hour and 28 days of age, an amount of a mycobacterial cell wall extract, wherein the amount is effective to activate the immune system of the newborn animal.
4. The method of any one of Claims 1 to 3, wherein the mycobacterial cell wall extract is prepared from family *Mycobacteriaceae*, genus *Mycobacterium*, or species *Mycobacterium phlei*.
5. The method of any one of Claims 1 to 4, wherein activation of the immune system comprises activation of white blood cells.
6. The method of Claim 5, wherein the white blood cells are selected from the group consisting of T-lymphocytes and monocytes.
7. The method of Claim 6, wherein the T-lymphocytes are CD4<sup>+</sup> T lymphocytes.
8. The method of Claim 7, wherein the CD4<sup>+</sup> T lymphocytes are CD25<sup>+</sup>CD4<sup>+</sup> T lymphocytes or MHC Class II<sup>+</sup>CD4<sup>+</sup> T lymphocytes.
9. The method of Claim 6, wherein the monocytes are MHC Class II<sup>+</sup> monocytes.
10. The method of Claim 5, wherein the activated white blood cells display enhanced production of IFN- $\gamma$  in response to a stimulus.
11. A method of enhancing production performance of an animal comprising administering to the animal within the first 24 hours of age, an amount of a

mycobacterial cell wall extract, wherein the amount is effective to enhance production performance of the animal.

12. A method of enhancing production performance of an animal comprising administering to the animal between 1 hour and 4 days of age, an amount of a mycobacterial cell wall extract, wherein the amount is effective to enhance production performance of the animal.

13. A method of enhancing production performance of an animal comprising administering to the animal between 1 hour and 28 days of age, an amount of a mycobacterial cell wall extract, wherein the amount is effective to enhance production performance of the animal.

14. The method of any one of Claims 11 to 13, wherein the mycobacterial cell wall extract is prepared from family *Mycobacteriaceae*, genus *Mycobacterium*, or species *Mycobacterium phlei*.

15. The method of any one of Claims 11 to 13, wherein the enhancement of production performance is an increase in the average daily weight gain of the animal or an increase in efficiency of feed use.

16. The method of any one of Claims 11 to 13, wherein the enhancement of production performance is a decrease in the mortality of the animal, a decrease in the number of treatment days necessary to maintain the health of the animal, a decrease in the cost of treatment necessary to maintain the health of the animal, or any combination thereof.

17. The method of any of the preceding claims wherein the animal is a mammal, bird, fish, amphibian or crustacean.

18. The method of any of the preceding claims wherein the animal is domestic food animal.

19. The method of claim 18, wherein the domestic food animal is a calf, a chick, a piglet, a kid, a fawn or a lamb.

20. The method of claim 18, wherein the domestic food animal is a calf of a domestic cow.

21. The method of claim 18, wherein the domestic food animal is a chick of a domestic fowl.
22. The method of any of the preceding claims wherein the mycobacterial cell wall extract is combined with a pharmaceutically acceptable carrier.
23. The method of any of preceding claims wherein the administration is subcutaneous, intravenous, intramuscular, intraperitoneal or oral.
24. The method of any of the preceding claims wherein the amount of the mycobacterial cell wall extract administered to the animal is from about 0.001  $\mu\text{g}$  per kg to about 600  $\mu\text{g}$  per kg, about 0.01  $\mu\text{g}$  per kg to about 400  $\mu\text{g}$  per kg, or about 0.1  $\mu\text{g}$  per kg to about 200  $\mu\text{g}$  per kg per dose.
25. Use of a mycobacterial cell wall extract in a treatment for activating the immune system of a newborn animal, wherein the mycobacterial cell wall extract is administered to the animal within the first 24 hours of age, between 1 hour and 4 days of age, or between 1 hour and 28 days of age, in an amount effective to activate the immune system.
26. Use of a mycobacterial cell wall extract in a treatment for enhancing production performance of an animal, wherein the mycobacterial cell wall extract is administered to the animal within the first 24 hours of age, between 1 hour and 4 days of age, or between 1 hour and 28 days of age, in an amount effective to enhance production performance.
27. Use of a mycobacterial cell wall extract for the manufacture of a medicament useful as a treatment for activating the immune system of a newborn animal, wherein the medicament is administered to the animal within the first 24 hours of age, between 1 hour and 4 days of age, or between 1 hour and 28 days of age, .
28. Use of the mycobacterial cell wall extract for the manufacture of medicament useful as a treatment for enhancing production performance of an animal, wherein the medicament is administered to the animal within the first 24 hours of age, between 1 hour and 4 days of age, or between 1 hour and 28 days of age.

29. The use of any of Claims 25 to 28, wherein the mycobacterial cell wall extract is prepared from family *Mycobacteriaceae*, genus *Mycobacterium*, or species *Mycobacterium phlei*.

30. The use of any of Claims 26 or 28, wherein the enhancement of production performance is an increase in the average daily weight gain of the animal or an increase in efficiency of feed use.

31. The use of any of Claims 26 or 28, wherein the enhancement of production performance is a decrease in the mortality of the animal, a decrease in the number of treatment days necessary to maintain the health of the animal, a decrease in the cost of treatment necessary to maintain the health of the animal, or any combination thereof.

Substitute Sheet 19

AMENDED SHEET